



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CANHAM

Atty. Ref.: 124-796

Appl. No. 09/647,599

Group: 1615

Filed: October 03, 2000

Examiner: Ware

For: Implants for administering substances and methods of producing implants

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TECH CENTER 1600/2900

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF PRIOR INVENTION UNDER 37 C.F.R. §1.131

I, Leigh Trevor Canham, a British subject, hereby declare as follows:

1. That I am an inventor of the above-identified application and I reside in Malvern, Great Britain.
2. That I am the sole inventor of WO 97/06101 (WO '101).
3. That WO '101 does not describe resorbable mesoporous silicon having a drug located in its pores.
4. Resorbable silicon is disclosed (paragraph spanning pages 12 and 13) but resorbable mesoporous silicon having a drug located in its pores is not disclosed. The use of bioactive silicon for drug delivery is disclosed (p 6, lines 5 to 6 and p 16, lines 5-6) but the use of resorbable mesoporous silicon for drug delivery is not disclosed. The impregnation of porous silicon with calcium is described (p 14, lines 2 to 10) but resorbable mesoporous silicon having a drug located in its pores is not described.

WO '101 contains speculation that polycrystalline silicon impregnated with calcium could have a higher solubility than bulk crystalline silicon in simulated body fluid (p 14, lines 18 to 21) however polycrystalline silicon is not the same as porous silicon.

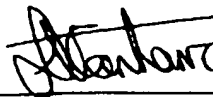
5. That the main uses of bioactive silicon, described in WO '101, are: (a) use as a material suitable for forming a bond with bone or tissue (p3, lines 3-5, p6, lines 2-3, p15, lines 24 to 26, p22, lines 13 to 14) and (b) use as an implant packaging material, particularly for electronic devices (p2, lines 25-29, p3, lines 5 to 6, p6, lines 2-3, p22, lines 15 to 16).

6. Resorbable materials would generally not be used for packaging electronic devices to be used in a human/animal body, or for bonding with bone/tissue. This is because the resorbable materials would erode when implanted.

7. WO '101 describes the possible use of resorbable silicon for the promotion of bioactivity (p 13, lines 5 to 8), and also describes the impregnation of porous and polycrystalline silicon with calcium for the promotion of bioactivity (p 14, lines 2 to 23). However, there is no disclosure in WO '101, either implicit or explicit, that links the use of resorbable mesoporous silicon to drug delivery.

That I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 12th August 2003



Leigh Trevor Canham